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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,584	10/11/2005	Shyam S Mohapatra	USF-183XCI	4246
23557 7590 08/07/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER LI, QIAN JANICE	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 08/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,584

Applicant(s)

MOHAPATRA, SHYAM S

Examiner

Q. Janice Li, M.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 20, 21, 23-25 and 27-42 is/are pending in the application.
- 4a) Of the above claim(s) 31-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15, 20, 21, 23-25 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, and species election drawn to SEQ ID No: 5 in the response filed 6/13/07 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-12, 14, 16-19, 22, 26 have been canceled. Claims 27-42 are newly submitted. Claims 31-42 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 13, 15, 20, 21, 23-25, 27-30 are under current examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/319,529, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the provisional application fails to disclose SEQ ID No: 5. Thus, the priority date for the elected species, SEQ ID No: 5 has been established as the filing date of the PCT application, i.e. 9/8/03.

Claim Objections

Claim 13 is objected to because of the following informalities: claim 13 encompasses multiple inventions as indicated in the Restriction requirement. Upon election of an invention for prosecution, the claim should be amended so that it only reads on the elected invention. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 15, 20, 21, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by *Lin et al* (Hum Gene Ther 1998;9:1429-38), and as evidenced by *Lin et al* (Hypertension 1995;26:847-53).

Lin et al teach a pharmaceutical composition comprising a nucleic acid sequence encoding a 28-amino acid peptide hormone ANP (instant SEQ ID No: 4, e.g. 1st paragraph of the reference and page 4 of *Lin et al* 1995), adenoviral expression vectors comprising the nucleic acid (e.g. fig. 1), and host 293 cells comprising the vector. The vector was administered intravenously to rats in a pharmaceutical carrier, and it genetically modified cells of the rats. Accordingly, *Lin et al* anticipate instant claims.

Claims 20, 21, 23-25, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by *Seidman et al* (Science 1984;226:1206-9, IDS).

Seidman et al teach an expression vector comprising a nucleic acid sequence encoding a natriuretic peptide hormone NHP, which comprising the amino acid sequence as identified by SEQ ID No: 5, and host cells comprising the vector were used at least for propagating the vector. Accordingly, *Seidmen et al* anticipate instant claims.

Claims 13, 15, 20, 21, 23-25, 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by *Shimkets* (US 6,013,630).

Shimkets teach a pharmaceutical composition comprising a nucleic acid sequence encoding a mutant natriuretic factor (ANF), while the preferred embodiment is a mutant of a 28-amino acid peptide (SEQ ID No: 1) of the rat or human ANF as depicted in fig. 2, which differs from instant SEQ ID No: 5 by one amino acid at residue position 1. *Shimkets* goes on to teach the preferred mutant has a mutation at amino acid position 1 of SEQ ID No: 1, and most preferably the mutation at position 1 of SEQ

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ID No: 1 is a substitution of the glycine residue with a serine (column 2, lines 36-46). As such the mutant is identical to instantly claimed SEQ ID No: 5. *Shimkets* teach nucleic acid encoding the peptide (e.g. SEQ ID No: 3), and vectors and host cells comprising the nucleic acid (§ 5.2). *Shimkets* also teach the vectors could be used as a therapeutic agent in a pharmaceutical carrier in gene therapy (§ 5.3.2). Accordingly, *Shimkets* anticipate instant claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

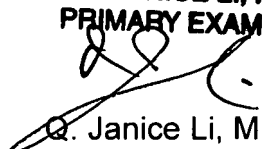
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

**Q. JANICE LI, M.D.
PRIMARY EXAMINER**



Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL

August 2, 2007